UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,038	05/06/2005	Michel Serpelloni	0600-1040	9708

466 7590 06/09/2008

YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,038	SERPELLONI, MICHEL	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 3/7/08 are acknowledged.

2. Claim 10 was amended.

3. Claims 24-30 were added.

4. Claims 10-30 are pending and are included in the prosecution.

Response to Arguments

Claim Objections

5. In light of Applicant's amendment of claim 10, the objection of 12/7/07 is withdrawn.

Rejection of claims 10-23 under 35 USC § 103(a)

6. Applicant's arguments, see Page 9, filed 3/7/08, with respect to the rejection of claims 10-23 under 35 U.S.C. § 103(a) as being unpatentable over Tsukuda et al. (US 2002/0146487) in view of Fouache et al. (US 6,630,586) have been fully considered but are not persuasive.

Applicant argues that Tsukuda is not directed to a method of preparing granules of active substances with branched maltodextrins as recited in the claimed invention. Applicant argues that Tsukuda does not use the "not readily digestible" carbohydrate as a granulation binder, rather, Tsukuda applies the "not readily digestible binder" to the surface of the granule.

This is not found persuasive because Tsukuda teaches a dry blend comprising soybean protein and a not readily digestible carbohydrate (Page 2, [0020]). Therefore, a

mixture or blend of the soybean protein and a not readily digestible carbohydrate is formed, which is then granulated (Page 3, [0030]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine this teaching of Tsukuda with the branched maltodextrins of Fouache and arrive at the instant method for preparing granules.

Applicant states the surprising and unexpected discovery that the viscosity (of solutions containing the branched maltodextrins) does not in any way impair the formulation of the active substances, whatever the granulation method chosen the incorporation of the branched maltodextrins into a mixture with active substances, which exhibit little or no particular capacity for granulation, makes it unexpectedly possible to prepare granules having both excellent mechanical properties and physical properties.

This is not found persuasive because one with ordinary skill in the art would find it obvious to substitute the not readily digestible carbohydrate of Tsukuda with the branched maltodextrins of Fouache in the process of granulating an active ingredient such as the powdered soybean protein taught by Tsukuda.

Therefore, the rejection of 12/7/07 is maintained.

7. New claims 24-30 are also included in this final rejection.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10-23 remain rejected and new claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukuda et al. (US 2002/0146487) in view of Fouache et al. (US 6,630,586).

The claimed invention is a method for preparing granules of active substances containing dietary fiber. The method consists of granulating a mixture of the active substances and branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most 4500g/mol. The branched maltodextrins content is between 3 and 13% by weight of the mixture to be granulated.

Tsukuda teaches “a method for preparing an easily dispersible granule of soybean protein, which comprises the step of granulating powdery soybean protein while the powder is sprayed with an aqueous solution containing a carbohydrate which is not readily digestible, characterized by using at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein … the granulation is fluidized bed-granulation” (Page 2, [0020]). A “dry blend comprising soybean protein and a not readily digestible carbohydrate is prepared, and is then sprayed with lecithin in water to produce a lecithin-coated soybean protein carbohydrate blend. The water is then removed … by drying. Other components, including nutraceutical components … can be combined with the protein/carbohydrate/lecithin blend to further supplement the nutritive value of the product” (Pages 2-3, [0021]). The method steps are: “stirring and

fluidizing powdery soybean protein according to an appropriate method, spraying the stirred and fluidized powdery soybean protein with the carbohydrate in the form of an aqueous solution, followed by appropriately drying the spray-coated soybean protein powder after the spraying step or simultaneous with the spraying operation to thus coat the surface of the soybean protein powder with the carbohydrate and to simultaneously granulate the soybean protein" (Page 3, [0030]). "After completion of the drying, the resulting granules are passed through a sieve, for instance, to make the particle size uniform and then packaged" (Page 3, [0036]). "Examples of the not readily digestible carbohydrates commercially available are …Fibersol 2 (trade name of hardly digestible dextrin available from Matsutani Industry Co., Ltd., …" (Pages 5-6, [0055]).

Tsukuda does not expressly teach branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most 4500g/mol.

Fouache teaches branched maltodextrins with "22 and 35% … glucosidic linkages 1→6, a content of reducing sugars lower than 20%, a polymolecularity index lower than 5 and a number molecular weight Mn at most equal to 4500g/mole" (Col. 2, lines 37-42). An acariogenic composition comprising branched maltodextrins and at least one polyol (chosen from sorbitol, mannitol, xylitol and maltitol) is disclosed (Col. 4, lines 15-19). "The content of glucosidic linkages 1→6, of between 22 and 35%, gives the branched maltodextrins … a character of indigestibility, the consequence of which is

to reduce their calorific value by preventing their assimilation at the level of the small intestine" (Col. 2, lines 45-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of granulating a powder (soybean protein) while the powder is sprayed with an aqueous solution containing a carbohydrate which is not readily digestible, as taught by Tsukuda, combine it with the branched maltodextrins as the carbohydrate which is not readily digestible, as taught by Fouache, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Fouache teaches that the branched maltodextrins are indigestible and a further motivation is that by using the branched maltodextrins, a low calorie composition can be prepared.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 10, 24 and 30, the method for preparing granules would have been obvious to one skilled in the art over the method for preparing granules taught by Tsukuda (Page 2, [0020]). The step of granulating active substances would have been obvious over granulating the powdery active substance (powdered soybean

protein) as taught by Tsukuda (Page 2, [0020]). The step of mixing the active substance with branched maltodextrins would have been obvious over mixing or dry blending soybean protein and a not readily digestible carbohydrate as taught by Tsukuda (Pages 2-3, [0021]), in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The content of the branched maltodextrins (between 3 and 13% by weight of the mixture to be granulated) would have been obvious over the "at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein" taught by Tsukuda (Page 2, [0020]). The limitation of the active substance would have been obvious over the active ingredient soybean protein taught by Tsukuda (Page 2, [0020]).

Regarding instant claims 11-16 and 25-28, the limitation of the active substances selected from starches and starch derivatives (claim 11), dextrins (claim 12), hydrogenated starch hydrolysates (claim 13), polyols (claims14-15) and sugars, strong sweeteners and pharmaceutical active principles (claim 16) would have been obvious over the granulation method with the active ingredient soybean protein, as taught by Tsukuda (Page 2, [0020]), in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). One skilled in the art would know that granulation is used as a method to improve the flow characteristics, and reduce dustiness of a powder. One skilled in the art would know that granulation is a step carried out prior to tableting and therefore, would use substances such as starch and starch derivatives, dextrins, hydrogenated starch hydrolysates, polyols, sugars and strong (or intense) sweeteners as active substances for granulation.

Regarding instant claims 17 and 29, the method steps would have been obvious over the method of mixing the dry blend of the powdery active substance and the "not readily digestible carbohydrate" with lecithin and water (18.98%), drying and passing the granules through a sieve as taught by Tsukuda (Page 3, [0036] and Page 8, Example 5, [0098]).

Regarding instant claim 18, the limitation of approximately 5% maltodextrin would have been obvious over the "at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein" as taught by Tsukuda (Page 2, [0020]).

Regarding instant claim 19, the limitation of 10% of water to form the wet powders would have been obvious over the amount of water (18.98%) taught by Tsukuda (Page 2, [0020]). Although Tsukuda does not expressly teach 10% of water, one with ordinary skill in the art would modify the level of water during the process of routine experimentation in order to optimize the wet granulation process. The recited percentage would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 20, the solution of branched maltodextrins would have been obvious over the "aqueous solution containing a carbohydrate which is not readily digestible" as taught by Tsukuda (Page 2, [0020]) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The limitation of the solids content would have been obvious over the 10% of "carbohydrate which is not readily digestible" used by Tsukuda (Page 7, Example 1 and Page 8, Table 1). The limitation of spraying the solution of branched maltodextrins onto the powder of active substances and recovering

and drying the granules would have been obvious over the spraying of the carbohydrate solution on the active powder (soybean protein) and drying the granules, as taught by Tsukuda (Page 7, [0071]).

Regarding instant claim 21, the solids content of 25% of the solution of branched maltodextrins would have been an obvious variant over the solids content taught by Tsukuda (Page 7, Example 1 and Page 8, Table 1) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42), unless there is evidence of criticality or unexpected results.

Regarding instant claim 22, the content of approximately 5% of the solution of branched maltodextrins would have been obvious over the "at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein" as taught by Tsukuda (Page 2, [0020]).

Regarding instant claim 23, the use of branched maltodextrins as a granulation binder would have been obvious over the "carbohydrate which is not readily digestible" as taught by Tsukuda (Page 2, [0020]).

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615